Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): enzootic bovine leukosis (EBL)

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Assessment of listing and categorisation of animal diseases within the framework of the Animal Health Law (Regulation (EU) No 2016/429): enzootic bovine leukosis (EBL)

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Abstract

Enzootic bovine leucosis (EBL) has been assessed according to the criteria of the Animal Health Law (AHL), in particular criteria of Article 7 on disease profile and impacts, Article 5 on the eligibility of EBL to be listed, Article 9 for the categorisation of EBL according to disease prevention and control rules as in Annex IV and Article 8 on the list of animal species related to EBL. The assessment has been performed following a methodology composed of information collection and compilation, expert judgement on each criterion at individual and, if no consensus was reached before, also at collective level. The output is composed of the categorical answer, and for the questions where no consensus was reached, the different supporting views are reported. Details on the methodology used for this assessment are explained in a separate opinion. According to the assessment performed, it is inconclusive whether EBL can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL because there was no full consensus on the criteria 5 B(i) and 5 B(iii). Consequently, since it is inconclusive whether EBL can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL, then the assessment on compliance of EBL with the criteria as in Sections 4 and 5 of Annex IV to the AHL, for the application of the disease prevention and control rules referred to in points (d) and (e) of Article 9(1), and which animal species can be considered to be listed for EBL according to Article 8(3) of the AHL is also inconclusive.

Keywords: Enzootic bovine leukosis, EBL, bovine leukaemia virus, BLV, Animal Health Law, listing, categorisation, impact

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1. Introduction

1.1. Background and Terms of Reference as provided by the requestor

The background and Terms of Reference (ToR) as provided by the European Commission for the present document are reported in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the Animal Health Law (AHL) framework (EFSA AHAW Panel, 2017).

1.2. Interpretation of the Terms of Reference

The interpretation of the ToR is as in Section 1.2 of the scientific opinion on the ad hoc methodology followed for the assessment of the disease to be listed and categorised according to the criteria of Article 5, Annex IV according to Article 9, and 8 within the AHL framework (EFSA AHAW Panel, 2017).

The present document reports the results of assessment on enzootic bovine leukosis (EBL) according to the criteria of the AHL articles as follows:

- Article 7: EBL profile and impacts
- Article 5: eligibility of EBL to be listed
- Article 9: categorisation of EBL according to disease prevention and control rules as in Annex IV
- Article 8: list of animal species related to EBL.

2. Data and methodologies

The methodology applied in this opinion is described in detail in a dedicated document about the ad hoc method developed for assessing any animal disease for the listing and categorisation of diseases within the AHL framework (EFSA AHAW Panel, 2017).

3. Assessment

3.1. Assessment according to Article 7 criteria

This section presents the assessment of EBL according to the Article 7 criteria of the AHL and related parameters (see Table 2 of the opinion on methodology (EFSA AHAW Panel, 2017)), based on the information contained in the fact-sheet as drafted by the selected disease scientist (see Section 2.1 of the scientific opinion on the ad hoc methodology) and amended by the AHAW Panel.

3.1.1. Article 7(a) Disease Profile

3.1.1.1. Article 7(a)(i) Animal species concerned by the disease

Susceptible animal species

Parameter 1 – Naturally susceptible wildlife species (or family/orders)

A single report on detection of bovine leukaemia virus (BLV) antibodies in one free-ranging European bison (*Bison bonasus*) from Poland has been published (Kita and Anusz, 1991). Otherwise, under natural conditions, BLV has not been found in any wild ruminants like deer, llama, antelopes. Other species have been suspected but not confirmed as naturally susceptible species (e.g. capybara, rhesus monkeys, chimpanzees) (EFSA AHAW Panel, 2015).

Parameter 2 – Naturally susceptible domestic species (or family/orders)

The following species are considered naturally susceptible among domestic species:

- *Bos taurus* (domestic cattle),
- *Bos indicus* (zebu),
- *Bubalus bubalis* (water buffalo) (EFSA AHAW Panel, 2015),
- *Bos grunniens* (yak) (Ma et al., 2016).

Spill over to other domesticated ungulates may occur (primarily in BLV high prevalent areas). The species having been affected are:

- *Ovis aries* (domestic sheep) (Green et al., 1988; Pannwitz et al., 1988; Kunakov and Abakin, 1993; Nekoei et al., 2015),
- *Vicugna pacos* (Huacaya alpaca) (Lee et al., 2012).

Parameter 3 – Experimentally susceptible wildlife species (or family/orders)

No experimentally susceptible wildlife species are known.

Parameter 4 – Experimentally susceptible domestic species (or family/orders)

The following species have been subject to successful experimental infection:

- *Ovis aries* (domestic sheep),
- *Capra aegagrus hircus* (domestic goat),
- *Oryctolagus cuniculus* (common rabbit) (EFSA AHAW Panel, 2015).

Reservoir animal species

Parameter 5 – Wild reservoir species (or family/orders)

There are no wild reservoir species.

Parameter 6 – Domestic reservoir species (or family/orders)

The following domestic species are considered natural reservoir of the disease:

- *Bos taurus* (domestic cattle),
- Other domesticated bovine animals depending on region: *Bos indicus* (zebu), *Bubalus bubalis* (water buffalo),
- *Bos grunniens* (mutus) (yak).

3.1.1.2. Article 7(a)(ii) The morbidity and mortality rates of the disease in animal populations

Morbidity

Parameter 1 – Prevalence/Incidence

The EBL-free Member States (MSs) or regions thereof are laid down in the newest version of Commission Decision 2003/467/EC[1]. It was recently amended by Commission Implementing Decision (EU) 2017/888[2]. Officially free MSs are now Belgium, the Czech Republic, Denmark, Germany, Estonia, Ireland, Spain, Cyprus, Latvia, Lithuania, Luxembourg, the Netherlands, Austria, Poland, Slovenia, Slovakia, Finland, Sweden, France (except Reunion Island), the United Kingdom, and in addition, some provinces in Italy, and Portugal.

On the other hand, the results of the surveillance up to 2015 are presented in the annual report 'Bovine and Swine Diseases – Situation 2015'.[3] The overall herd prevalence was 0.12% by serological test (827,000 bovine herds tested in European Union (EU)), and 0.01% by examination of bulk milk samples (84,361 bovine herds tested). The between-herd serological prevalence in MSs with seroprevalence > 0 is reported in Table 1. Prevalence estimates of BLV infection in the USA, Argentina, Chile, Japan, and select areas of Canada, China and Iran are reported in Table 2.

The between-herd prevalence of BLV in non-European countries are summarised in Table 2.

[1] 2003/467/EC: Commission Decision of 23 June 2003 establishing the official tuberculosis, brucellosis, and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds. OJ L 156, 25.6.2003, p. 74–78.

[2] Commission Implementing Decision (EU) 2017/888 of 22 May 2017 amending Decision 2003/467/EC as regards the official tuberculosis-free status of the region of Umbria of Italy and of the enzootic-bovine-leukosis-free status of Poland, amending Decision 2004/558/EC as regards the infectious bovine rhinotracheitis-free status of Germany, and amending Decision 2008/185/EC as regards the Aujeszky's disease-free status of certain regions of Poland and the approval of the eradication programme for Aujeszky's disease for the region of Veneto of Italy. OJ L 135, 24.5.2017, p. 27–34.

[3] https://ec.europa.eu/food/sites/food/files/animals/docs/la_bovine_final_report_2015.pdf

Table 1: Seroprevalence of BLV infection in infected MSs in 2015

Member state	% infected herds against tested	Number of bovine herds tested	Total no. of herds
Bulgaria	12.95%	1,228	71,850
Greece	1.09%	2,580	38,951
Croatia	0.30%	17,647	32,753
Hungary	0.52%	7,533	16,243
Italy	0.01%	26,175	75,457
Lithuania	0.18%	14,008	64,771
Latvia	0.03%	6,803	26,286
Malta	2.47%	162	182
Poland	0.05%	74,186	526,033*
Portugal	0.02%	5,828	33,426
Romania	0.11%	599,754	600,937

*: Empty herds and herds with animals under 24 months of age – 43,426; The figures include also not officially free regions (zachodniopomorskie voivodship: bialogardzki, choszczenski, drawski, goleniowski, kolobrzeski, lobeski, pyrzycki, stargardzki, walecki regions): with 2,492 herds in which 2 infected herds were detected, and 99,91% free herds.
Source: European Commission (2015).

Table 2: Prevalence of BLV infection in the USA, Argentina, Chile, Japan and select areas of Canada, China and Iran

Country (year)	Animal prevalence	Herd prevalence	Reference
Canada (2002) province Manitoba province Alberta	60.8% (dairy cattle) 10.3% (beef cattle) 26.9% (dairy cattle)	97.4% (dairy cattle) 47.9% (beef cattle) 86.7% (dairy cattle)	VanLeeuwen et al., (2006) Scott et al., (2006)
USA (2007)		83.9% (dairy cattle)	APHIS (2008)
Argentina (2001)	32.9% (dairy cattle)	84% (dairy cattle)	Trono et al. (2001)
Chile (2009)		59% (dairy cattle)	Felmer et al. (2009)
Japan (2011)	35.2% (dairy and beef cattle)	78% (dairy cattle) 69% (beef cattle)	Murakami et al. (2013)
China North-East (2014) 6 provinces 15 provinces	18.3% (dairy and beef cattle) 49.1% (dairy cattle) 1.6% (beef cattle)	21.24% (dairy and beef cattle)	Sun et al. (2015) Yang et al. (2016)
Iran Isfahan Province	81.9% (dairy cattle)		Morovati et al. (2012)

Parameter 2 – Case-morbidity rate (% clinically diseased animals out of infected ones)

Infected animals, after a latency that extends from a few months to several years, develop a polyclonal proliferation of B cells called persistent lymphocytosis in 30–50% of cases. Persistent lymphocytosis is usually stable for several years but it may also evolve to lymphoma, a malignant tumour of lymphoid tissue, which is the main clinical manifestation of BLV infection. Animals with persistent lymphocytosis have a higher probability of developing lymphoma, thus it is considered as a pre-tumour stage (EFSA AHAW Panel, 2015).

Regarding lymphoma frequency, the development of lymphomas is a late manifestation of BLV infection, because lymphomas are recorded at the end of the productive life of animals (at slaughter, at death or euthanasia in the herd). The number of animals developing lymphomas is usually recorded per year in the population at risk (period prevalence), but more often it is recorded at slaughter during meat inspection as the prevalence of animals condemned due to lymphoma. The difficulty in assessing the lymphoma impact over time is that seldom both lymphoma incidence and prevalence of BLV infection are known (EFSA AHAW Panel, 2015). In Europe before and in the early phases of eradication period, prevalence of 1% in dairy cows have been recorded for example in Germany, corresponding to 2–5% of adult cows developing disease. Similarly in Sweden, lymphomas were diagnosed in approximately 1% of slaughtered cows during the early 1960s from high-prevalence regions. In more recent times, in the USA the period prevalence in slaughtered cows 2005–2007 was

0.8%, while in Canada prevalence in slaughter cattle in high BLV-prevalence region in the period 1999–2012 was 0.5% (EFSA AHAW Panel, 2015).

Due to the uncertainty in estimating the frequency of lymphomas due to BLV infection, in countries with modern dairy production systems and no control programme for EBL, the best estimate of the cumulative lymphoma incidence in BLV-infected cows is 1–2%, mostly in cattle older than 3–5 years. In high prevalence herds, the cumulative lymphoma incidence among dairy cows may reach 5%.

The morbidity and mortality due to EBL in the EU is currently negligible as a consequence of strict control measures applied since the 1990s. Since 2011, only 19 confirmed lymphoma cases have been reported from all MSs (European Commission, 2011a, 2012, 2013, 2014, 2015).

Mortality

Parameter 3 – Case-fatality rate

The malignant tumoral form of BLV infection (lymphomas) invariably lead to death of the animal within months, thus with a case-fatality rate of 100% (EFSA AHAW Panel, 2015).

3.1.1.3. Article 7(a)(iii) The zoonotic character of the disease

Presence

Parameter 1 – Report of zoonotic human cases (anywhere)

BLV genome sequences have been found in breast cancer tissue, but no evidence has indicated an aetiological role of BLV in human disease (Buehring et al., 2001, 2014, 2015; Baltzell et al., 2009).

3.1.1.4. Article 7(a)(iv) The resistance to treatments, including antimicrobial resistance

Parameter 1 – Resistant strain to any treatment even at laboratory level

No treatment is applied, thus no resistance to treatment is reported.

3.1.1.5. The persistence of the disease in an animal population or the environment

Animal population

Parameter 1 – Duration of infectious period in animals

Following infection animals carry virus for the remainder of their life in lymphocytes and are potentially infectious lifelong. Animals with high viral load are shown to be more infectious compared to low viral load animals (EFSA AHAW Panel, 2015).

Parameter 2 – Presence and duration of latent infection period

A few weeks after infection, the viral load in blood reaches the level turning the animal potentially infectious (EFSA AHAW Panel, 2015).

Parameter 3 – Presence and duration of the pathogen in healthy carriers

The majority of infected animals do not show any signs of the disease or the signs are very mild and unspecific, while 5–10% of BLV-infected animals can develop lymphoma 3–5 years after infection (EFSA AHAW Panel, 2015).

Environment

Parameter 4 – Length of survival (dpi) of the agent and/or detection of DNA in selected matrices (soil, water, air) from the environment (scenarios: high and low T)

BLV is associated to cells and viral particles are not excreted in free forms in the environment. Infected cells may survive for a limited time in blood or milk, they are sensitive to freezing and high temperatures and are readily inactivated by UV light, thereby losing the ability to replicate and transmit BLV. BLV-infected cultured cells heated to 60°C or higher for 1 min did not infect inoculated cells. *In vitro* at 4°C the BLV in cells survived in blood containing anticoagulant and BLV antibodies for at least 2 weeks. In blood without BLV antibodies, the virus survived at least for 4 weeks (EFSA AHAW Panel, 2015).

3.1.1.6. Article 7(a)(vi) The routes and speed of transmission of the disease between animals, and, when relevant, between animals and humans

Routes of transmission

Parameter 1 – Types of routes of transmission from animal to animal (horizontal, vertical)

Horizontal: Any mechanism able to transmit blood or infected lymphocytes between animals should be considered.

- Direct

Contact with body excretions containing BLV-infected lymphocytes (e.g. saliva, milk) may result in infection of susceptible animals.

The risk of transmission of BLV via semen or embryos has been considered negligible, whereas natural mating with infected bulls may lead to transmission due to intense direct contact on mating.

- Indirect

Iatrogenic transmission via use of blood-contaminated needles, instruments for tattooing or dehorning, contaminated gloves for rectal palpation is possible. The use of milking machines compared to manual milking has also been associated with BLV infection (EFSA AHAW Panel, 2015).

Haematophagus insects (flies) may contribute to the spread of BLV within a herd by mechanically transferring lymphocytes via biting. Horse flies (*Tabanus* spp.) may have greater potential to transmit BLV within herds.

Vertical: Transplacental transmission and/or peri-partum infection may account for 10–25% of infections (EFSA AHAW Panel, 2015)

Parameter 2 – Types of routes of transmission between animals and humans (direct, indirect, including food-borne)

This route is not known, although alimentary route has been suggested with unpasteurised bovine milk containing BLV-infected cells (EFSA AHAW Panel, 2015).

Speed of transmission

Parameter 3 – Incidence between animals and, when relevant, between animals and humans

The rate of transmission between animals is dependent on the within herd prevalence in specific herds. Herd management factors (like housing system, calving management) may impact the spread of the virus within herd (Table 3).

Table 3: Occurrence of BLV infection within a longitudinal study of a number of dairy herds (USA and Italy) and the dairy population (Australia and Estonia) for various years between 1972 and 1992

Population	Prevalence*	Annual incidence*	Reference
USA, dairy herd longitudinal study (1972–1982)	20–34% 12–18%	9.5–18.3% 2.1–5.5%	Kaja et al. (1984)
Australia, dairy herd	42%	24%	Dimmock et al. (1991)
Italy, 9 dairy herds longitudinal study (1976–1980)	11.0–11.7%	3.9%	Rutili et al. (1982)
Estonia, dairy cattle national population (1989–1992)	31.4% 27.2% 14.0% 3.3%	20.7% 12.8% 4.9% 2.8%	Viltrop and Laht (1996)

*: At animal level.

The incidence rate (determined by seroconversion and/or detection of provirus) varies in different age groups. Perinatal transmission to newborn calves is observed in a minority of births (3–11.5%) from infected dams. The incidence increases around first lactation (EFSA AHAW Panel, 2015).

Parameter 4 – Transmission rate (beta) (from R_0 and infectious period) between animals and, when relevant, between animals and humans

Significant differences in transmission parameters have been reported as shown in Table 4.

Table 4: Transmission rate of BLV infection

Parameter (CI 95%)	Population	Reference
β = 2.9 (95% CI 1.9–3.7) per year R_0 = 8.9	Dairy cattle, Argentina	Monti et al. (2007)
β = 0.62 (0.37-0.89) in 5 months ~ 1.5/year	Dairy cattle, Japan	Tsutsui et al. (2010)

3.1.1.7. Article 7(a)(vii) The absence or presence and distribution of the disease in the Union, and, where the disease is not present in the Union, the risk of its introduction into the Union

Presence and distribution

Parameter 1 – Map where the disease is present in EU

The EBL-free MSs and regions are laid in the newest version of Commission Decision 2003/467/EC amended by Commission Implementing Decision (EU) 2017/888, and they are listed in Section 3.1.1.2.

Figure 1 shows the seroprevalence up to 2015 presented in the annual report 'Bovine and Swine Diseases – Situation 2015[3]'.

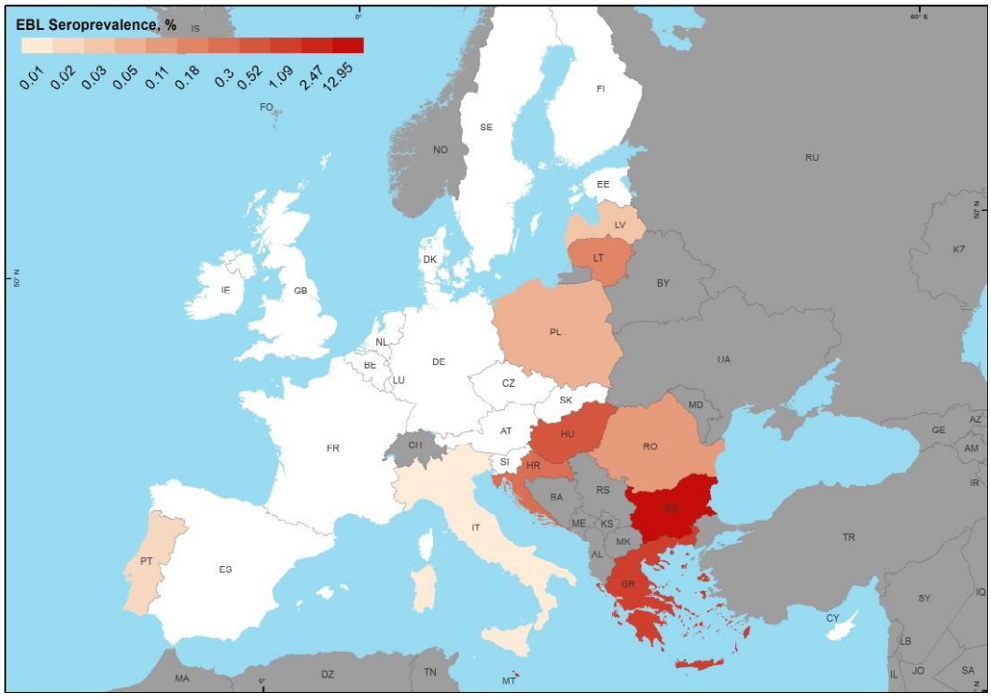

Figure 1: Reported seroprevalence of BLV infection in EU up to 2015

Parameter 2 – Type of epidemiological occurrence (sporadic, epidemic, endemic) at MS level

In countries where EBL is still present, the epidemiological occurrence can be considered endemic.

Risk of introduction

Risk of introduction is estimated at EU level. As BLV is present in the EU, this is not assessed here.

3.1.1.8. Article 7(a)(viii) The existence of diagnostic and disease control tools

Diagnostic tools

See Section 3.1.4.1.

Control tools

Parameter 2 – Existence of control tools (Table 5)

Table 5: Control tools for EBL (EFSA AHAW Panel, 2015)

Goal/method	Tool/components	Applicability
Eradication – elimination of infected animals	Whole herd slaughter	Small herds. Low herd prevalence of the infection. Support for restocking available
	'Test and slaughter': Regular testing and prompt culling of infected animals Culling of the offspring of infected animals Safe management practices implied to avoid spread of the virus between animals	Low or moderate within herd prevalence Freedom can be achieved if the rate of removal of positive animals exceeds the annual incidence rate of infection Compensation for culled animals.
	'Test and separate': Physically separating the infected cattle from uninfected Gradual elimination of infected animals by increased culling frequency in infected group regular testing of seronegative group and prompt separation or elimination of positive animals In the final stage of the eradication programme 'test and slaughter' strategy is applied Safe management practices implied to avoid spread of the virus between animals	High within herd prevalence. Physical separation possible Compensation for culled animals
Control – reduction of the rate of effective contacts	Safe herd management practices: Milk from BLV-negative cows or milk replacer to feed calves. Milk from BLV-infected cows can be used after freezing or heat treatment Chemical dehorning or cautery Disposable needles or needles sterilised by boiling between animals Cleaning and disinfection of equipment used to assist calving, ear tattooing, feeding and giving medication between animals Separate gloves for rectal exploration Separate calving paddocks for BLV-infected and uninfected cattle Removal of calves from cows within 24 hours of birth but after intake of colostrum Fly control programme	All herds
Prevention – avoiding introduction	Biosecurity measures: Introduction of animals from certified BLV infection free herds Avoiding contacts with infected animals (e.g. common pastures) Avoiding iatrogenic introduction	All herds

Goal/method	Tool/components	Applicability
Surveillance – maintaining disease/ infection free status	At herd level: Serological surveillance – regular testing of individual or pooled milk or serum samples for BLV antibodies At region or country level: Surveillance for tumours at post-mortem inspection of slaughter animals Serological surveillance – regular testing of representative sample of herds for BLV antibodies from bulk milk samples or individual milk or serum samples	Free herds/territories

3.1.2. Article 7(b) The impact of diseases

3.1.2.1. Article 7(b)(i) The impact of the disease on agricultural and aquaculture production and other parts of the economy

The level of presence of the disease in the Union

Parameter 1 – Number of MSs where the disease is present

The MSs that are not officially free from BLV infection are Bulgaria, Greece, Croatia, Hungary, Italy, France, Lithuania, Latvia, Malta, Portugal and Romania (See Sections 3.1.1.2 and 3.1.1.7).

The loss of production due to the disease

Parameter 2 – Proportion of production losses (%) by epidemic/endemic situation

On EU level, the losses can be considered negligible due to low prevalence. On regional and herd level the losses may be significant.

Tumours: As explained in Section 3.1.1.2, the losses due to EBL lymphoma in the EU is currently negligible (less than 20 cases since 2011), as a consequence of strict control measures applied since the 1990s. In countries where no control programme is in place and with modern dairy production systems, the cumulative lymphoma incidence among dairy cows may reach 5% (EFSA AHAW Panel, 2015).

Milk production: Since the impact of BLV infection on reduction of milk yield is difficult to assess from observational studies because of the influence of age, herd size, lactation number and genetic potential, the selection of study design and methods to consider possible confounders is important. The results of the systematic review conducted by EFSA in 2015 are summarised in Table 6.

Table 6: Reduction of milk yield in dairy cows in high-performing dairy herds

Population	Indicator/value	Reference
Sweden, national dairy cattle population	2.5% lower milk production in BLV-infected herds vs non-infected	Emanuelson et al. (1992)
US, 1,006 dairy herds in 20 states	218 kg per cow (3%) less milk in herds with test-positive cows produced compared to herds with no test-positive cows	Ott et al. (2003)
US, Michigan	11.5 kg per cow per year for each percentage-point increase in the within-herd prevalence of BLV-infected cows	Erskine et al. (2012)
10,670 Holstein cows from 364 herds in 8 provinces of Canada	11,000 kg/cow less milk compared to the test-negative cows over their entire study lifespan	Nekouei et al. (2016b)

Reproduction: The impact is not known and controversial. An increased calving interval in BLV-positive cows – up to 2 weeks, but there are studies where significant impact of BLV infection was not identified (EFSA AHAW Panel, 2015).

Mastitis: The impact on udder health is also controversial, while some studies reported an increased level of somatic cells in milk in BLV-infected cows, in particular for cows with persistent lymphocytosis,

but other studies did not detect significant differences between BLV-positive and -negative animals. The clinical significance of these findings remains inconclusive (EFSA AHAW Panel, 2015).

Cow longevity: the impact on cow longevity is summarised in Table 7.

Table 7: Impact of BLV infection to cattle longevity

Population	Estimate	Reference
10,670 Holstein cows from 364 herds in 8 provinces of Canada	The difference in the probability of culling or death between the BLV positive and negative cohorts gradually increased, from 13.4% at the second lactation to 26.2% at the seventh lactation	Nekouei et al. (2016a)
3,849 Holstein dairy cows in 112 herds in Michigan, US	BLV-positive cows were 23% more likely than their BLV-negative herd mates to die or be culled	Bartlett et al. (2013)
~ 4200 dairy cows in 104 Michigan dairy herds, US	Herds with higher rates of BLV had significantly lower longevity	Erskine et al. (2012)
Sweden, national dairy cattle population	Significantly higher rate of culling in BLV infected herds v. non infected	Emanuelson et al. (1992)

3.1.2.2. Article 7(b)(ii) The impact of the disease on human health

The impact on human health is estimated only for zoonotic diseases. There is no scientific grounds to classify EBL as a zoonotic disease, thus this aspect is not relevant.

3.1.2.3. Article 7(b)(iii) The impact of the disease on animal welfare

Parameter 1 – Severity of clinical signs at case level and related level and duration of impairment

The development of tumours is accompanied by chronic ill health, progressive loss of body condition, weakness, anaemia and anorexia, attributable to infiltration of tumours into various internal organs. Tumours are not likely to be detected until they cause conspicuous pathophysiological manifestations. The animal welfare consequences in terms of duration and severity may vary according to the location and magnitude of the spread of tumours in organs, e.g. heart, kidneys, lungs, central nervous system or gastrointestinal system. Overall, animals will suffer when tumours have progressed beyond early stages. It is also likely that BLV-infected cattle suffer considerably during the last months of their lives due to immunosuppression. In addition, the EBL has significant impact on cow longevity being a cause of early culling of affected animals. (EFSA AHAW Panel, 2015)

3.1.2.4. Article 7(b)(iv) The impact of the disease on biodiversity and the environment

Biodiversity

Parameter 1 – Endangered wild species affected: listed species as in CITES and/or IUCN list

Registered cases of BLV infection in susceptible wildlife species are rare (EFSA AHAW Panel, 2015). There are 29 potentially BLV susceptible species of Bovidae family in the list of endangered species of CITES (2016). There is no evidence of BLV infection in endangered species in wildlife.

Parameter 2 – Mortality in wild species

Due to slow development of the disease, the increased mortality due to the disease occurs in older age classes. Therefore, the potential of the infection to cause increased mortality in wild populations is not known, it may be most likely minor.

Environment

Parameter 3 – Capacity of the pathogen to persist in the environment and cause mortality in wildlife

The capacity of the BLV to persist in the environment is very low (see parameter 3, Section 3.1.1.5). The risk of spreading of the infection to wildlife populations through environmental contamination can be considered negligible.

3.1.3. Article 7(c) Its potential to generate a crisis situation and its potential use in bioterrorism

BLV is not listed as pathogen to be used in bioterrorism, and due to the epidemiological characteristics of the disease, has a negligible potential to generate a crisis.

3.1.4. Article 7(d) Feasibility, availability and effectiveness of the following disease prevention and control measures

3.1.4.1. Article 7(d)(i) Diagnostic tools and capacities

Availability

Parameter 1 – Officially/internationally recognised diagnostic tool, OIE certified

Internationally recognised diagnostic tools according to OIE are listed in Table 8.

Table 8: Internationally recognised diagnostic tools for EBL (OIE, 2016a)

Aim	Matrix	Diagnostic test	Test characteristics
Antibody detection	Serum individual	Agar gel immunodiffusion test (AGID)	Minimal analytical sensitivity: reference serum E05 diluted 1:10 in negative serum should be detected as positive (Council Directive 64/432/EEC[(a)])
	Serum individual and pooled Milk individual and pooled	Enzyme-linked immunosorbent assay (ELISA) Indirect and blocking	More sensitive than AGID Test sensitivity and specificity depend on test system and matrix E05 reference serum is used to define analytical sensitivity of a test
BLV-proviral DNA detection	Tumour tissue Peripheral blood mononuclear cells	Nested polymerase chain reaction (PCR)	Analytical sensitivity: 5-10 target molecules of proviral DNA
Virus isolation	Peripheral blood mononuclear cells	*In vitro* culture of peripheral blood mononuclear cells from infected animals. The p24 and gp51 antigens can be detected in the supernatant of the cultures by radio-immunoassay (RIA), ELISA, immunoblot or AGID. The presence of the BLV particles can be demonstrated by electron microscopy and BLV-proviral DNA by PCR	NA
Typing of tumours	Tumour tissue	Histological examination[(1)]	NA

(a): Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine. OJ 121, 29.7.1964, p. 1977–2012.
(1): Not OIE certified method for diagnosis of EBL. Histological examination supports the diagnosis of malignant tumours but is not able to distinguish between sporadic lymphomas and those induced by BLV.

Effectiveness

Parameter 2 – Se and Sp of diagnostic test

Limited information exist on the diagnostic accuracy of available diagnostic tests. Most test evaluations have compared enzyme-linked immunosorbent assay (ELISA) and agar gel immunodiffusion test (AGID) and found the former to be equally or more sensitive. Relative to infection, Klintevall et al. (1991) reported that the ELISA test is capable of detecting herds with within-herd prevalences of 4–5%.

Feasibility

Parameter 3 – Type of sample matrix to be tested (blood, tissue, etc.)

See Parameter 1.

3.1.4.2. Article 7(d)(ii) Vaccination

There are no vaccines available.

3.1.4.3. Article 7(d)(iii) Medical treatments

There is no medical treatment available.

3.1.4.4. Article 7(d)(iv) Biosecurity measures

Availability

Parameter 1 – Available biosecurity measures

BLV is almost exclusively transmitted between herds by movement of infected live cattle. Iatrogenic transmission contributes mainly to the spread within herd although between herds transmission cannot be completely excluded via use of blood-contaminated needles, instruments for tattooing or dehorning as well as rectal palpation using contaminated gloves.

The biosecurity measures directed to eliminate these routes of transmission are:

- Introduction of animals from certified BLV infection free herds
- Avoiding contacts with infected animals (e.g. common pastures, during transportation, mating)
- Avoiding iatrogenic introduction:
  - Use of disposable needles or needles sterilised by boiling
  - Use of cleaned and disinfected equipment to assist calving, for ear tattooing, feeding and medication etc.
  - Use of clean gloves for rectal exploration
  - Etc.

(EFSA AHAW Panel, 2015).

Effectiveness

Parameter 2 – Effectiveness of biosecurity measures in preventing the pathogen introduction

Biosecurity measures have proved to be very effective in avoiding introduction of the virus to free herds (EFSA AHAW Panel, 2015).

Feasibility

Parameter 3 – Feasibility of biosecurity measures

The biosecurity measures applied are part of good farming practice and general hygienic measures, thus do not involve additional expenditures from farmers or governmental institutions if official BLV control programme is in place including certification of free herds.

3.1.4.5. Article 7(d)(v) Restrictions on the movement of animals and products

Availability

Parameter 1 – Available movement restriction measures

In Council Directive 64/432/EEC are laid down movement requirements all bovine categories (Article 6(2)). Pursuant to Council Directive 98/46/EC, Annex D, Chapter 1B,[4] one of the conditions for officially EBL-free herd to retain its free status is, that (ii) 'any animals introduced into the herd come from an officially EBL-free herd'.

Thus, the movement restrictions on animals from herds not officially free are partial as they can be moved to other herds of the same health status.

[4] Council Directive 98/46/EC of 24 June 1998 amending Annexes A, D (Chapter I) and F to Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine. OJ L 198, 15.7.1998, p. 22–39.

Pursuant to Article 6 Point 3, animals from herds not officially EBL free are not allowed to move to slaughter in another MS.

Effectiveness

Parameter 2 – Effectiveness of restriction of animal movement in preventing the between farm spread

BLV is almost exclusively transmitted between herds by movement of infected live cattle. Movement restrictions have proved to be an effective tool in preventing the spread between herds (EFSA AHAW Panel, 2015).

Feasibility

Parameter 3 – Feasibility of restriction of animal movement

The movement restrictions are applied at herd level and these restrictions allow limited movement of animals within the country to herds of the same health status as well as to slaughter without restrictions. Thus, the movement restrictions do not cause severe consequences to the normal farm functioning. The impact of these restrictions to farm economy is related to restricted possibilities to sell live animals for breeding (EFSA AHAW Panel, 2015).

3.1.4.6. Article 7(d)(vi) Killing of animals

Availability

Parameter 1 – Available methods for killing animal

For the eradication of the disease, the selective slaughter of infected animals ('test and slaughter' strategy) is applied. Culled animals undergo normal slaughter at abattoirs.

Effectiveness

Parameter 2 – Effectiveness of killing animals (at farm level or within the farm) for reducing/stopping spread of the disease

Prompt culling of infected animals from herds has proven to be the most effective disease eradication measure (EFSA AHAW Panel, 2015).

Feasibility

Parameter 3 – Feasibility of killing animals

Culled animals undergo normal slaughter at abattoirs, thus the process of killing of animals does not imply any specific arrangements and doesn't have any extra economic or animal welfare consequences.

The possible impact of killing of infected animals on farm economy is related to loss of animals before the end of their productive life. These losses can be considered minor compared to the positive effects of the disease freedom status on herd health and welfare as well as farm economy.

3.1.4.7. Article 7(d)(vii) Disposal of carcasses and other relevant animal by-products

Parameter 1 – Available disposal option

Animals undergo normal slaughter at abattoirs and their by-products are disposed according to general rules and regulations for slaughterhouses.[5,6] The disposal of by-products in slaughterhouse facilities guarantees the destruction of the virus without environmental consequences. If parts of the carcasses showing signs of the disease are not fit for human consumption, those and the blood of such animals have to be categorised as animal-by products of Category 2 which often implies higher disposal costs and certain ABP uses are not allowed (e.g. pet food).

[5] Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation). OJ L 300, 14.11.2009, p. 1–33.

[6] Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive Text with EEA relevance OJ L 54, 26.2.2011, p. 1–254.

3.1.5. Article 7(e) The impact of disease prevention and control measures

3.1.5.1. Article 7(e)(i) The direct and indirect costs for the affected sectors and the economy as a whole

Parameter 1 – Cost of control (e.g. treatment/vaccine, biosecurity)

The cost of control measures depend on type of measures applied in a farm. Control by improved biosecurity does not cause significant additional expenditures for farmers as biosecurity measures applied are part of good farming practice and general hygienic measures.

If control measures include testing of animals and regrouping/separating infected animals, then costs are increasing accordingly.

In US the mean annual cost of a test-and-manage control programme was estimated to be 1,765 dollars per herd. The cost of control varied with herd size (Rhodes et al., 2003).

Parameter 2 – Cost of eradication (culling, compensation)

The main costs of the eradication programmes have been related to regular testing of cattle herds, and compensation for slaughtered infected animals. Some additional costs may be associated with regrouping and separation of infected animals in high prevalence herds as well as with improvement of biosecurity measures.

Between 2007 and 2011, the total cost incurred by the Health Service of Lazio Region (Italy) for the eradication of EBL was estimated in 6,134,694 EUR, of those about 2.5 million were the cost of the veterinarians labour, 8,864 for the transport, 23,908 for disposal and compensation for culled animals (Caminiti et al., 2016).

In 1993–2009, EU co-financed eradication programmes in MSs with €40,238,125. The measures funded contained: serological and milk tests of for cattle and cost incurred for compensation of the owners for the slaughter of animals (European Commission, 2011b). The financial contribution by the Community was 50% of the costs incurred by a MS. For 2009 the maximum of the costs reimbursed was €0.5 per laboratory test (ELISA or AGID) and €375 per culled animal (Decision 2008/897/EC[7]).

The EU contribution for EBL eradication programmes was provided to seven MSs (listed in Table 9) during the period 2005–2010. The estimated 6-year average annual costs (excluding sampling costs) were in all MSs less than €15 per herd or €11 or less per 10 cows in a national population, with the exception of Malta, where more funds were needed for compensations for culled animals due to higher BLV prevalence compared to the other six countries. In other MSs, the costs are mainly related to testing of cattle. The average annual expenditures in Malta (€1,019 per herd; €426 per 10 cows) reflect the extent of costs during the first phases of eradication, when significant proportion of animals has to be culled.

Table 9: Estimated costs of EBL eradication programmes in 2005–2010 in MSs with EU approved eradication programmes

Member State	No of cattle herds (2010)(1)	No of cows(2) (2010)(1)	EU support(3) €	Average total cost(4)€/year	Total €/herd per year	Total €/10 cows per year
Estonia	4,620	108,850	74,363	24,788	5,4	2,3
Italy	125,880	2,339,240	2,875,854	958,618	7,6	4,1
Latvia	35,100	184,000	263,519	87,840	2,5	4,8
Lithuania	93,050	370,050	295,346	98,449	1,1	2,7
Malta	290	6,930	887,285	295,762	1019,9	426,8
Poland	514,120	2,645,870	6,032,925	2,010,975	3,9	7,6
Portugal	50,040	720,030	2,370,781	790,260	15,8	11,0

(1): Eurostat.
(2): Dairy and beef breeds.
(3): European Commission (online).
(4): Calculated as two times EU support divided by 6 years.

[7] Commission Decision of 28 November 2008 approving annual and multi-annual programmes and the financial contribution from the Community for the eradication, control and monitoring of certain animal diseases and zoonoses presented by the Member States for 2009 and following years (notified under document number C(2008) 7415). OJ L 322, 2.12.2008, p. 39–49.

Parameter 3 – Cost of surveillance and monitoring

In regions free of EBL, continued surveillance is based on a combination of serological testing of adult animals and identification of tumours at slaughter (EFSA AHAW Panel, 2015).

The identification of tumours at slaughter is part of regular carcass inspection and the additional costs are related to laboratory investigation of suspect tumours (histology and PCR).

The monitoring of BLV free dairy herds is based on regular testing of individual or pooled (bulk) milk samples for BLV antibodies by ELISA test from all or representative sample of herds depending of the stage of the control programme (eradication or maintaining of the free status) (EFSA AHAW Panel, 2015).

The surveillance costs comprise of labour costs of managers of the programme as well as sample collectors, the cost of materials used for the blood and milk sampling, transportation costs related to farm visits and the delivery costs of samples and laboratory costs.

In Switzerland, the unit price per tested sample including labour, materials and general laboratory charges were estimated to be for a blood serum ELISA at 21.70 CHF and for bulk tank milk ELISA at 25 CHF including analysis of samples for BLV and Bovine Herpes Virus 1 antibodies (Reber et al., 2012).

Data provided in Table 9 largely reflect the costs of surveillance (except for Malta) in EU Member States as the main expenditures have been related to testing of cattle herds.

Parameter 4 – Trade loss (bans, embargoes, sanctions) by animal product

Pursuant to Council Directive 64/432/EEC, Annex D, Chapter 1B, one of the conditions for officially EBL free herd to retain its free status is, that (ii) 'any animals introduced into the herd come from an officially enzootic-bovine-leukosis-free herd'.

Thus, the movement restrictions to animals from not officially free herds are partial as they can be moved to other herd of the same health status.

Pursuant to Article 6 Point 3, animals from not officially EBL free herds are not allowed to move to slaughter in another member state.

According to Article 11.8.5 of the Chapter 11.8 of the OIE Terrestrial Animal Health Code, the imported animals should be free of BLV infection. The disease freedom of the animal has to be certified by the veterinary service of the exporting country (OIE, 2016b).

Parameter 5 – Importance of the disease for the affected sector (% loss or € lost compared to business amount of the sector)

Due to the successful eradication of EBL, the impact of the disease on agricultural production in MS is currently negligible. This statement is also valid for MS with low prevalence of infection but not yet officially free. However, the losses in affected herds are proportional to the within herd prevalence of the infection (EFSA AHAW Panel, 2015).

In United States, the estimated loss to the dairy industry in 1993 due to BLV caused milk and fat yields decline associated with persistent lymphocytosis (PL) only was more than $42 million annually in the situation where at least 50% of Holstein herds were infected with BLV and within infected herds 70% of animals were assumed to be infected and 20% of the infected animals develop PL (Da et al., 1993).

The loss of productivity in BLV positive dairy herds in USA resulted in a $285 million loss of economic surplus for producers and $240 million for consumers making a total of $525 million (Ott et al., 2003).

On herd level, the estimated mean cost to the producer per lymphoma case was 412 dollars and the mean annual cost of subclinical infection at a 50% prevalence of infection was 6,406 dollars per 100 milking cows in 2003 (Rhodes et al., 2003).

3.1.5.2. Article 7(e)(ii) The societal acceptance of disease prevention and control measures

There is no evidence of any societal non-acceptance towards EBL control programme.

The possible zoonotic potential of the BLV has been of some concern and has got some attention of general public in early years after discovery of the virus and more recently in connection with reports on discovery of the virus in breast tumours of humans.

3.1.5.3. Article 7(e)(iii) The welfare of affected subpopulations of kept and wild animals

Parameter 1 – Welfare impact of control measures on domestic animals

Implication of control measures does not cause any significant impairment of welfare compared to common herd management practices. More frequent sampling of animals (2–3 times a year) may cause some additional stress to animals if blood samples are taken. The level of stress caused is comparable to vaccination procedures. Infected animals are eliminated from the herd by normal slaughtering in regular abattoirs (EFSA AHAW Panel, 2015).

3.1.5.4. Article 7(e)(iv) The environment and biodiversity

Environment

Parameter 1 – Use and potential residuals of biocides or medical drugs in environmental compartments (soil, water, feed, manure)

Negligible – limited disinfection measures implied in farms.

3.2. Assessment according to Article 5 criteria

This section presents the results of the expert judgement on the criteria of Article 5 of the AHL about enzootic bovine leukosis (Table 10). The expert judgement was based on Individual and Collective Behavioural Aggregation (ICBA) approach described in detail in the opinion on the methodology (EFSA AHAW Panel, 2017). Experts have been provided with information of the disease fact-sheet mapped into Article 5 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 5, and the reasoning supporting their judgement.

The minimum number of judges in the judgement was eight. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 10: Outcome of the expert judgement on the Article 5 criteria for enzootic bovine leukosis

Criteria to be met by the disease: According to AHL, a disease shall be included in the list referred to in point (b) of paragraph 1 of Article 5 if it has been assessed in accordance with Article 7 and meets all of the following criteria		**Final outcome**
A(i)	The disease is transmissible	Y
A(ii)	Animal species are either susceptible to the disease or vectors and reservoirs thereof exist in the Union	Y
A(iii)	The disease causes negative effects on animal health or poses a risk to public health due to its zoonotic character	Y
A(iv)	Diagnostic tools are available for the disease	Y
A(v)	Risk-mitigating measures and, where relevant, surveillance of the disease are effective and proportionate to the risks posed by the disease in the Union	Y
At least one criterion to be met by the disease: In addition to the criteria set out above at points A(i)–A(v), the disease needs to fulfil at least one of the following criteria		
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	NC
B(ii)	The disease agent has developed resistance to treatments and poses a significant danger to public and/or animal health in the Union	na
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	NC
B(iv)	The disease has the potential to generate a crisis or the disease agent could be used for the purpose of bioterrorism	N
B(v)	The disease has or could have a significant negative impact on the environment, including biodiversity, of the Union	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC), red =not applicable (na), i.e. insufficient evidence or irrelevant to judge.

3.2.1. Non-consensus questions

This section displays the assessment related to each criterion of Article 5 where no consensus was achieved in form of tables (Tables 11 and 12). The proportion of Y, N or na answers are reported, followed by the list of different supporting views for each answer.

Table 11: Outcome of the expert judgement related to criterion 5 B(i)

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
B(i)	The disease causes or could cause significant negative effects in the Union on animal health, or poses or could pose a significant risk to public health due to its zoonotic character	NC	62	38	0

NC: non-consensus; number of judges: 8.

Reasoning supporting the judgement

Supporting Yes:

- In endemic areas within the EU, seroprevalence ranges from 0.01% to 12% (2015), 0% to 1–2% of BLV-infected animals can develop lymphomas. Furthermore, there is evidence that BLV-infected herds register a reduction in milk yield.

Supporting No:

- The probability to develop lymphomas over the lifespan of the animals is low.

Table 12: Outcome of the expert judgement related to criterion 5 B(iii)

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
B(iii)	The disease causes or could cause a significant negative economic impact affecting agriculture or aquaculture production in the Union	NC	62	38	0

NC: non-consensus; number of judges: 8.

Reasoning supporting the judgement

Supporting Yes:

- On EU level, the losses can be considered negligible due to low prevalence following decades of control programmes. On regional and herd level, the losses may be significant.
- In herds with test-positive cows compared to herds with no test-positive cows, a reduction in milk yield of 3% has been observed (218 kg/cow). Over the entire study lifespan, the test-positive herd produced 11,000 kg/cow less milk compared to the test-negative. In MSs currently BLV-free and where dairy production is important, such as Denmark or Ireland, these losses would cause a significant negative economic impact.
- EBL has a significant impact on milk yield (Table 6) and longevity (Table 7), and can be a cause of early culling of affected animals (EFSA AHAW Panel, 2015). At present, there may be limited impact of the disease in the Union due to a long-term eradication programme, but if disease barriers are removed, the prevalence would be expected to increase and could thus cause significant negative effects in the Union.

Supporting No:

- In endemic situations, 1–2% of BLV-infected cattle develop lymphosarcoma, whereas in herds with higher infection prevalence, up to 5%. Lymphosarcoma is one of the main causes of condemnation of adult dairy cows at slaughter. However, lymphoma is rarely seen in animals younger than 2 years of age and is most common in the 4- to 8-year-old age group. Therefore, most of the affected animals, especially in the dairy sector, will be slaughtered before the development of lymphoma or before symptoms are evident. In these animals, lymphomas are generally found as an incidental post-mortem finding.

- Experiences from US and Canada should be extrapolated to Europe with care due to important differences in farm size and structure. Prevalence is generally low and consequences are therefore not significant.

3.2.2. Outcome of the assessment of EBL according to criteria of Article 5(3) of the AHL on its eligibility to be listed

As from the legal text of the AHL, a disease is considered eligible to be listed as laid down in Article 5 if it fulfils all criteria of the first set from A(i) to A(v) and at least one of the second set of criteria from B(i) to B(v). According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. According to the results shown in Table 10, EBL complies with all criteria of the first set, but not with at least one criterion of the second set because the assessment is inconclusive on compliance with criteria 5 B(i) and 5 B(iii). Therefore, it is inconclusive whether EBL can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL.

3.3. Assessment according to Article 9 criteria

This section presents the results of the expert judgement on the criteria of Annex IV referring to categories as in Article 9 of the AHL about EBL (Tables 13–17). The expert judgement was based on ICBA approach described in detail in the opinion on the methodology. Experts have been provided with information of the disease fact-sheet mapped into Article 9 criteria (see supporting information, Annex A), based on that the experts indicate their Y/N or 'na' judgement on each criterion of Article 9, and the reasoning supporting their judgement. The minimum number of judges in the judgement was eight. The expert judgement was conducted as described in the methodological opinion (EFSA AHAW Panel, 2017). For details on the interpretation of the questions, see Appendix B of the methodological opinion (EFSA AHAW Panel, 2017).

Table 13: Outcome of the expert judgement related to the criteria of Section 1 of Annex IV (category A of Article 9) for enzootic bovine leukosis (CI: current impact; PI: potential impact)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		Final outcome
1	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present in only in a very limited part of the territory of the Union	NC
2.1	The disease is highly transmissible	N
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects multiple species of kept and wild animals OR single species of kept animals of economic importance	Y
2.4	The disease may result in high morbidity and significant mortality rates	N
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic or pandemic potential OR possible significant threats to food safety	N
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N

5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 14: Outcome of the expert judgement related to the criteria of Section 2 of Annex IV (category B of Article 9) for enzootic bovine leukosis (CI: current impact; PI: potential impact)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Final outcome**
1	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	NC
2.1	The disease is moderately to highly transmissible	N
2.2	There be possibilities of airborne or waterborne or vector-borne spread	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease may result in high morbidity with in general low mortality	N
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, including epidemic potential OR possible significant threats to food safety	N
4	The disease has a significant impact on the economy of the Union, causing substantial costs, mainly related to its direct impact on the health and productivity of animals	N
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 15: Outcome of the expert judgement related to the criteria of Section 3 of Annex IV (category C of Article 9) for enzootic bovine leukosis (CI: current impact; PI: potential impact)

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Final outcome**
1	The disease is present in the whole OR part of the Union territory with an endemic character	N
2.1	The disease is moderately to highly transmissible	N
2.2	The disease is transmitted mainly by direct or indirect transmission	Y
2.3	The disease affects single or multiple species	Y
2.4	The disease usually does not result in high morbidity and has negligible or no mortality AND often the most observed effect of the disease is production loss	Y
At least one criterion to be met by the disease: In addition to the criteria set out above at points 1–2.4, the disease needs to fulfil at least one of the following criteria		
3	The disease has a zoonotic potential with significant consequences on public health, or possible significant threats to food safety	N
4	The disease has a significant impact on the economy of parts of the Union, mainly related to its direct impact on certain types of animal production systems	N
5(a)(CI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(a)(PI)	The disease has a significant impact on society, with in particular an impact on labour markets	N
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC
5(c)(CI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(c)(PI)	The disease has a significant impact on the environment, due to the direct impact of the disease OR due to the measures taken to control it	N
5(d)(CI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N
5(d)(PI)	The disease has a significant impact on a long-term effect on biodiversity or the protection of endangered species or breeds, including the possible disappearance or long-term damage to those species or breeds	N

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 16: Outcome of the expert judgement related to the criteria of Section 4 of Annex IV (category D of Article 9) for enzootic bovine leukosis

Criteria to be met by the disease: The disease needs to fulfil all of the following criteria		**Final outcome**
D	The risk posed by the disease in question can be effectively and proportionately mitigated by measures concerning movements of animals and products in order to prevent or limit its occurrence and spread	Y
The disease fulfils criteria of Sections 1, 2, 3 or 5 of Annex IV of AHL		NC

Colour code: green = consensus (Yes/No), yellow = no consensus (NC).

Table 17: Outcome of the expert judgement related to the criteria of Section 5 of Annex IV (category E of Article 9) for enzootic bovine leukosis

Diseases in category E **need to fulfil criteria of Sections 1, 2 or 3 of Annex IV of AHL** and/or the following:		**Final outcome**
E	Surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment (If a disease fulfils the criteria as in Article 5, thus being eligible to be listed, consequently category E would apply.)	NC

Colour code: yellow = no consensus (NC).

3.3.1. Non-consensus questions

This section displays the assessment related to each criterion of Annex IV referring to the categories of Article 9 of the AHL where no consensus was achieved in form of tables (Tables 18 and 19). The proportion of Y, N or 'na' answers are reported, followed by the list of different supporting views for each answer.

Table 18: Outcome of the expert judgement related to criterion 1 of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
1 (cat. A)	The disease is not present in the territory of the Union OR present only in exceptional cases (irregular introductions) OR present in only in a very limited part of the territory of the Union	NC	13	87	0
1 (cat. B)	The disease is present in the whole OR part of the Union territory with an endemic character AND (at the same time) several Member States or zones of the Union are free of the disease	NC	87	13	0

NC: non-consensus; number of judges: 8.

Reasoning supporting the judgement

Supporting Yes for 1 (cat. A):

- The disease is present in a limited part of the EU territory or only in exceptional cases as most MSs (18–28) (i.e. more than several) are EBL-free including the MSs with an important bovine population.

Supporting Yes for 1 (cat. B):

- Based on the map distribution of the disease in the EU, EBL is present in a limited part of the EU (mostly in the Balkans). Therefore, endemic infection is present in a very limited part of the EU cattle population, whereas several MSs or zones of the Union are free of the disease.

Table 19: Outcome of the expert judgement related to criterion 5(b) of Article 9

Question		Final outcome	Response		
			Y (%)	N (%)	na (%)
5(b)	The disease has a significant impact on animal welfare, by causing suffering of large numbers of animals	NC	25	75	0

NC: non-consensus; number of judges: 8.

Reasoning supporting the judgement

Supporting Yes:

- The prevalence of the disease can be significant, e.g. 60% (herd prevalence) in a Canadian study from 2002, and the impact as well.
- The animal welfare consequences in terms of duration and severity may vary according to the location and magnitude of the spread of tumours in organs, e.g. heart, kidneys, lungs, central nervous system or gastrointestinal system. Overall, animals will suffer when tumours have progressed beyond an early stage.
- In endemic countries, 1–2% of BLV-infected animals develop lymphomas (EFSA AHAW Panel, 2015) and in high prevalence herds the cumulative lymphoma incidence among dairy cows may reach 5%. In terms of welfare, these are large numbers of animals.

Supporting No:

- Experiences from the US and Canada should be extrapolated to Europe with care due to important differences in farm size and structure.

- Not a large number of animals are affected by the disease, and only the development of tumours in the last stages is a source of pain. The case-morbidity is overall negligible, even in animals that have lived long enough to show tumours.

3.3.2. Outcome of the assessment of criteria in Annex IV for EBL for the purpose of categorisation as in Article 9 of the AHL

As from the legal text of the AHL, a disease is considered fitting in a certain category (A, B, C, D or E corresponding to point (a) to point (e) of Article 9(1) of the AHL) if it is eligible to be listed for Union intervention as laid down in Article 5(3) and fulfils all criteria of the first set from 1 to 2.4 and at least one of the second set of criteria from 3 to 5(d) as shown in Tables 13–17. According to the assessment methodology (EFSA AHAW Panel, 2017), a criterion is considered fulfilled when the outcome is 'Yes'. With respect to different type of impact where the assessment is divided into current and potential impact, a criterion will be considered fulfilled if at least one of the two outcomes is 'Y' and, in case of no 'Y', the assessment is inconclusive if at least one outcome is 'NC'.

A description of the outcome of the assessment of criteria in Annex IV for EBL for the purpose of categorisation as in Article 9 of the AHL is presented in Table 20.

Table 20: Outcome of the assessment of criteria in Annex IV for EBL for the purpose of categorisation as in Article 9 of the AHL

Category	Article 9 criteria										
	1° set of criteria					2° set of criteria					
	1	2.1	2.2	2.3	2.4	3	4	5a	5b	5c	5d
	Geographical distribution	Transmissibility	Routes of transmission	Multiple species	Morbidity and mortality	Zoonotic potential	Impact on economy	Impact on society	Impact on animal welfare	Impact on environment	Impact on biodiversity
A	NC	N	Y	Y	N	N	N	N	NC	N	N
B	NC	N	Y	Y	N	N	N	N	NC	N	N
C	N	N	Y	Y	Y	N	N	N	NC	N	N
D	NC										
E	NC										

According to the assessment here performed, EBL complies with the following criteria of the Sections 1 to 5 of Annex IV of the AHL for the application of the disease prevention and control rules referred to in points (a) to (e) of Article 9(1):

1) To be assigned to category A, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment EBL complies with criteria 2.2 and 2.3, but not with criteria 2.1 and 2.4 and the assessment is inconclusive on compliance with criterion 1. To be eligible for category A, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and EBL does not comply with any of the criteria and the assessment is inconclusive on compliance with criterion 5b.
2) To be assigned to category B, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment EBL complies with criteria 2.2 and 2.3, but not with criteria 2.1 and 2.4 and the assessment is inconclusive on compliance with criterion 1. To be eligible for category B, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and EBL does not comply with any of the criteria and the assessment is inconclusive on compliance with criterion 5b.
3) To be assigned to category C, a disease needs to comply with all criteria of the first set (1, 2.1–2.4) and according to the assessment EBL complies with criteria 2.2, 2.3 and 2.4, but

not with 1 and 2.1. To be eligible for category C, a disease needs to comply additionally with one of the criteria of the second set (3, 4, 5a–d) and EBL does not comply with any of the criteria and the assessment is inconclusive on compliance with criterion 5b.

4) To be assigned to category D, a disease needs to comply with criteria of Section 1, 2, 3 or 5 of Annex IV of the AHL, whose assessment performed is inconclusive for EBL, and with the specific criterion D of Section 4, with which EBL complies.
5) To be assigned to category E, a disease needs to comply with criteria of Section 1, 2 or 3 of Annex IV of the AHL and/or the surveillance of the disease is necessary for reasons relating to animal health, animal welfare, human health, the economy, society or the environment. The latter is applicable if a disease fulfils the criteria as in Article 5 and the assessment here performed for EBL is inconclusive on compliance with the criteria as in Article 5.

3.4. Assessment of Article 8

This section presents the results of the assessment on the criteria of Article 8(3) of the AHL about EBL. The Article 8(3) criteria are about animal species to be listed, as it reads below:

'3. Animal species or groups of animal species shall be added to this list if they are affected or if they pose a risk for the spread of a specific listed disease because:

a) they are susceptible for a specific listed disease or scientific evidence indicates that such susceptibility is likely; or
b) they are vector species or reservoirs for that disease, or scientific evidence indicates that such role is likely'.

For this reason, the assessment on Article 8 criteria is based on the evidence as extrapolated from the relevant criteria of Article 7, i.e. the ones related to susceptible and reservoir species or routes of transmission, which cover also possible role of biological or mechanical vectors.[8] According to the mapping, as presented in Table 5, Section 3.2 of the scientific opinion on the ad hoc methodology (EFSA AHAW Panel, 2017), the main animal species to be listed for EBL according to the criteria of Article 8(3) of the AHL are as displayed in Table 21.

Table 21: Main animal species to be listed for EBL according to criteria of Article 8 (*source*: data reported in Section 3.1.1.1)

	Class	Order	Family	Genus/Species
Susceptible	Mammalia	Artiodactyla	Bovidae	*Bos taurus* (domestic cattle), *Bos indicus* (zebu), *Bubalus bubalis* (water buffalo), *Bos grunniens* (yak), *Ovis aries* (domestic sheep), *Bison bonasus* (European bison), *Capra aegagrus hircus* (domestic goat)
			Camelidae	*Vicugna pacos* (alpaca)
		Lagomorpha	Leporidae	*Oryctolagus cuniculus* (common rabbit)
Reservoir	Mammalia	Artiodactyla	Bovidae	*Bos taurus* (domestic cattle), *Bos indicus* (zebu), *Bubalus bubalis* (water buffalo), *Bos grunniens* (domestic yak)
Vectors	Insecta	Diptera	Tabanidae	*Tabanus* spp.*

*: Mechanical vectors.

4. Conclusions

TOR 1: *for each of those diseases an assessment, following the criteria laid down in Article 7 of the AHL, on its eligibility of being listed for Union intervention as laid down in Article 5(3) of the AHL;*

[8] A vector is a living organism that transmits an infectious agent from an infected animal to a human or another animal. Vectors are frequently arthropods. Biological vectors may carry pathogens that can multiply within their bodies and be delivered to new hosts, usually by biting. In mechanical vectors the pathogens do not multiply within the vector, which usually remains infected for shorter time than in biological vectors.

- According to the assessment here performed, it is inconclusive whether EBL can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL. Eligibility of listing EBL is dependent on a decision on criteria 5 B(i) and 5 B(iii).

TOR 2a: *for each of the diseases which was found eligible to be listed for Union intervention, an assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL;*

- According to the assessment here performed, since it is inconclusive whether EBL can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL, then also the assessment of its compliance with each of the criteria in Annex IV to the AHL for the purpose of categorisation of diseases in accordance with Article 9 of the AHL is inconclusive for the assignment to categories (d) and (e) of Article 9 of the AHL.

TOR 2b: *for each of the diseases which was found eligible to be listed for Union intervention, a list of animal species that should be considered candidates for listing in accordance with Article 8 of the AHL.*

- According to the assessment here performed, since it is inconclusive whether EBL can be considered eligible to be listed for Union intervention as laid down in Article 5(3) of the AHL, then it is also inconclusive which animal species can be considered to be listed for EBL according to Article 8(3) of the AHL.

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Abbreviations

AGID	agar gel immunodiffusion test
AHAW	EFSA Panel on Animal Health and Welfare
AHL	Animal Health Law
BLV	bovine leukaemia virus
CITES	Convention on International Trade in Endangered Species of Wild Fauna and Flora
CI	confidence intervals
EBL	Enzootic bovine leucosis
ELISA	enzyme-linked immunosorbent assay
ICBA	Individual and Collective Behavioural Aggregation
IUCN	International Union for Conservation of Nature
MS	Member State
OIE	World Organisation for Animal Health
PCR	polymerase chain reaction
PL	persistent lymphocytosis
RIA	radio-immunoassay
ToR	Terms of Reference